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Kaskoun et al.

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(54) **INTEGRATED CIRCUIT MODULE WITH LEAD FRAME MICRO-NEEDLES**

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(51) **Int. Cl.**

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H01L 23/48	(2006.01)
A61B 5/00	(2006.01)
H01L 21/48	(2006.01)
H01L 21/56	(2006.01)

(52) **U.S. Cl.**
CPC ***A61B 5/685*** (2013.01); ***H01L 21/4842*** (2013.01); ***H01L 21/565*** (2013.01); ***H01L 23/49541*** (2013.01); *A61B 2562/12* (2013.01)

(58) **Field of Classification Search**
CPC H01L 23/49555; H01L 23/49541; H01L 21/565
USPC 257/666, 697, 787, E23.031
See application file for complete search history.

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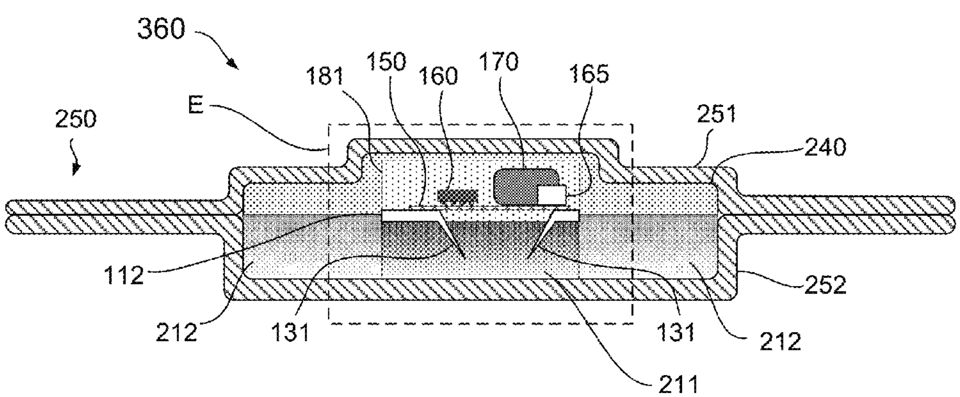
(57) **ABSTRACT**

An integrated circuit (IC) module with a lead frame micro-needle for a medical device, and methods of forming the IC module are described. The methods include forming a lead frame blank including a micro-needle integrally formed therein. The micro-needle may be bent beyond an initial lower side of the lead frame blank. The initial lower side may be joined with a protection layer such that the bent micro-needle is embedded in the protection layer, which may be removably attached to the initial lower side and the bent micro-needle. An IC component may be affixed to an upper side of the lead frame blank. The IC component and an upper surface of a core of the lead frame blank may be encapsulated with a molding compound forming a packaging of the IC module. Removal of the protection layer may expose the bent micro-needle projecting away from the packaging.

10 Claims, 9 Drawing Sheets



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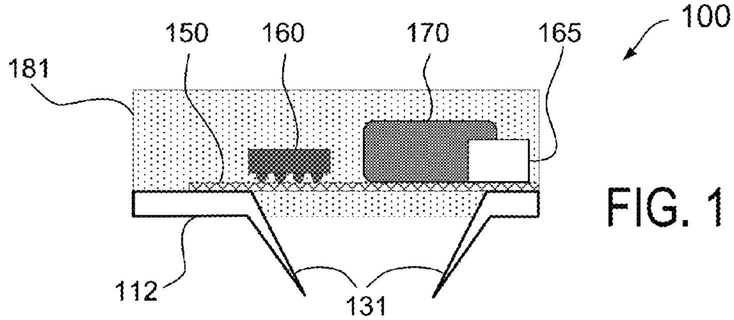


FIG. 1

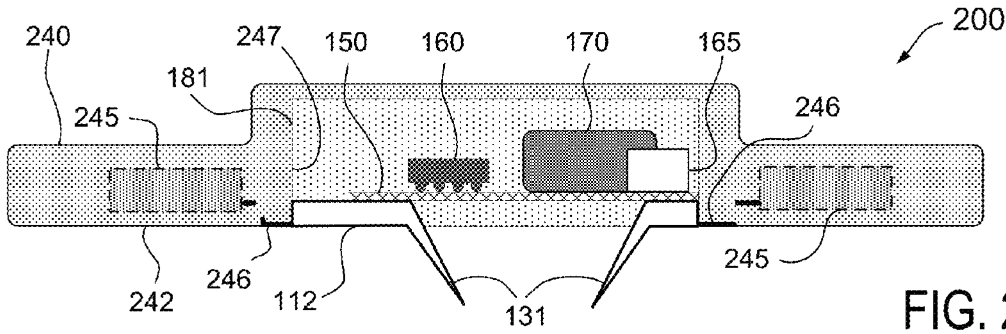


FIG. 2

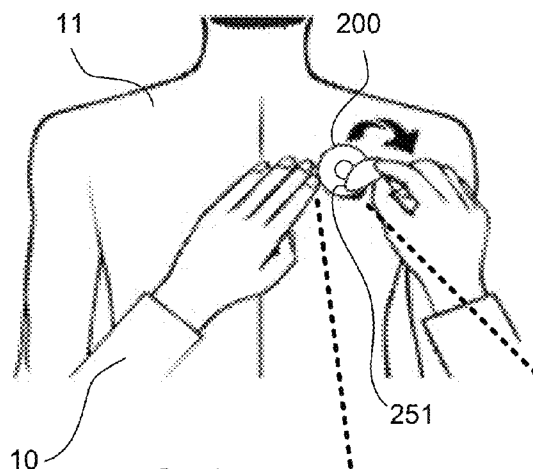


FIG. 3B

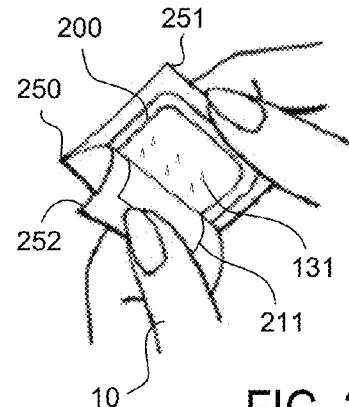


FIG. 3A

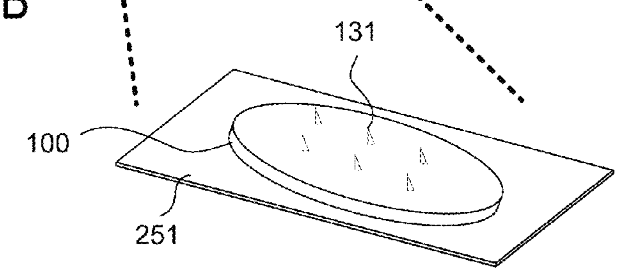


FIG. 3C

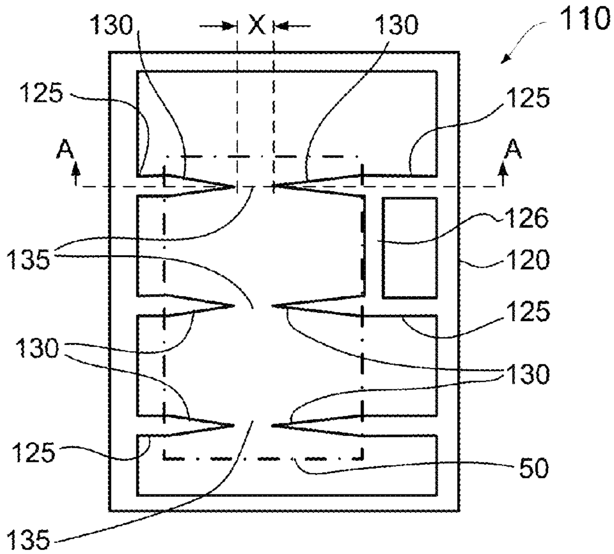


FIG. 4A

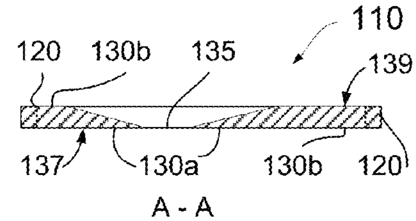


FIG. 4B

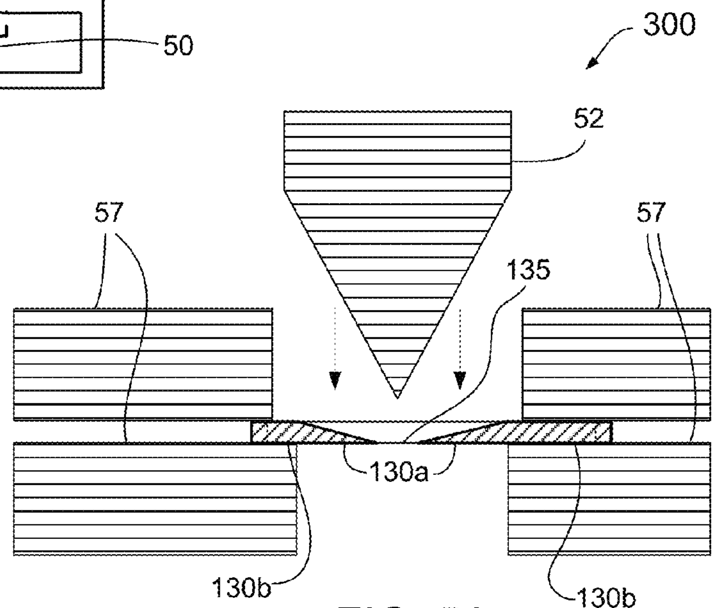


FIG. 5A

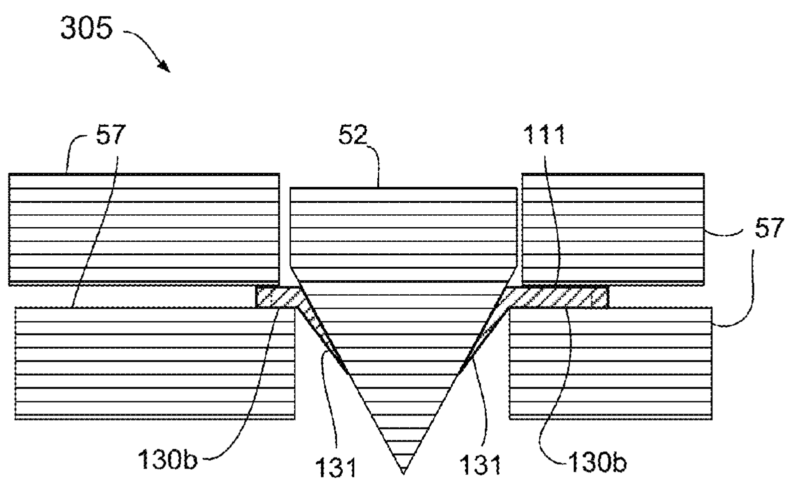


FIG. 5B

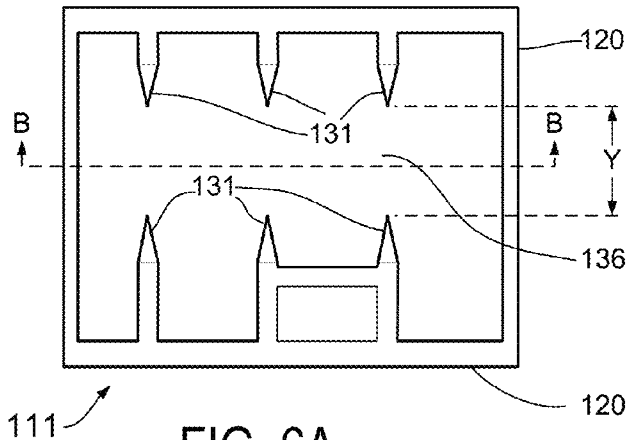


FIG. 6A

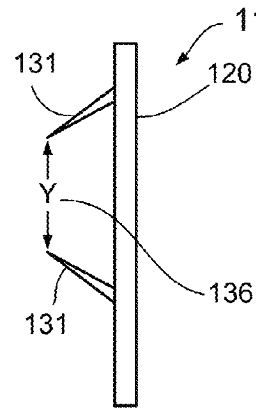


FIG. 6B

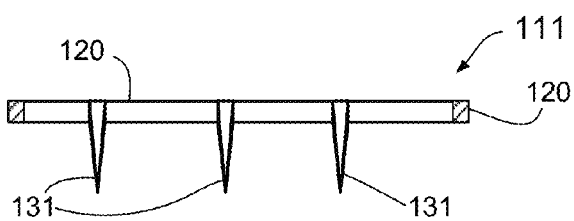


FIG. 6C

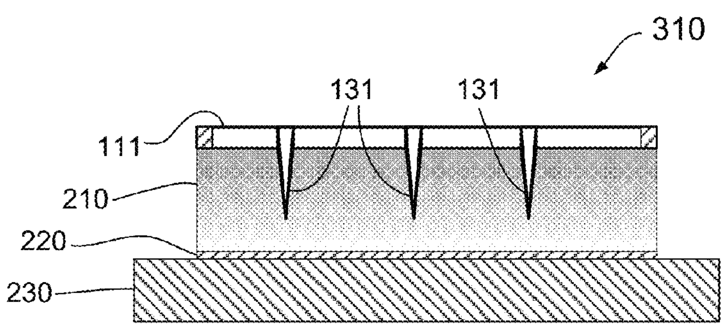


FIG. 7

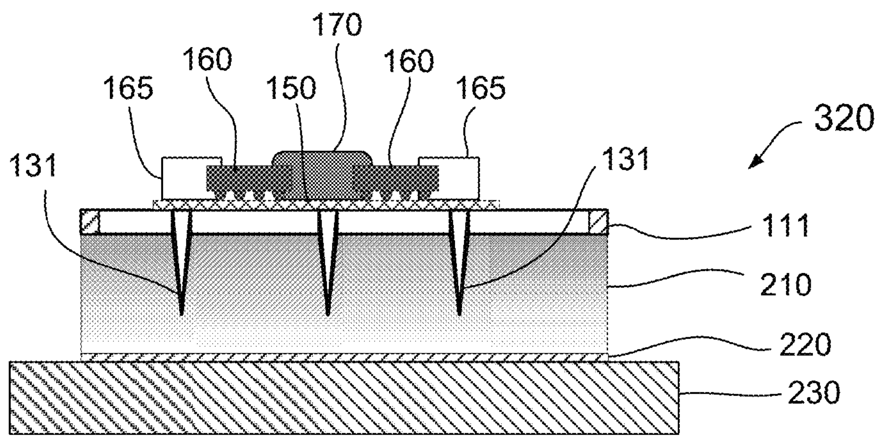

170
160
160
165
150
165
320
131
131
111
210
220
230

FIG. 8A

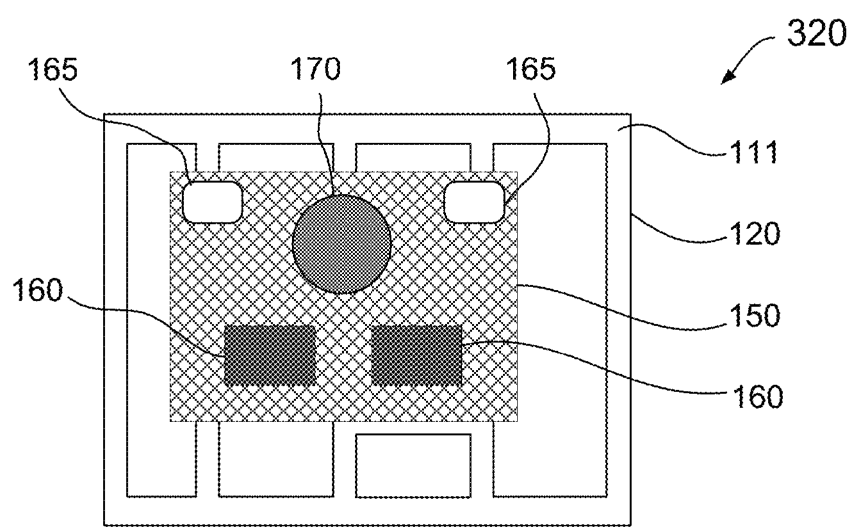

320
165
170
165
111
120
160
150
160

FIG. 8B

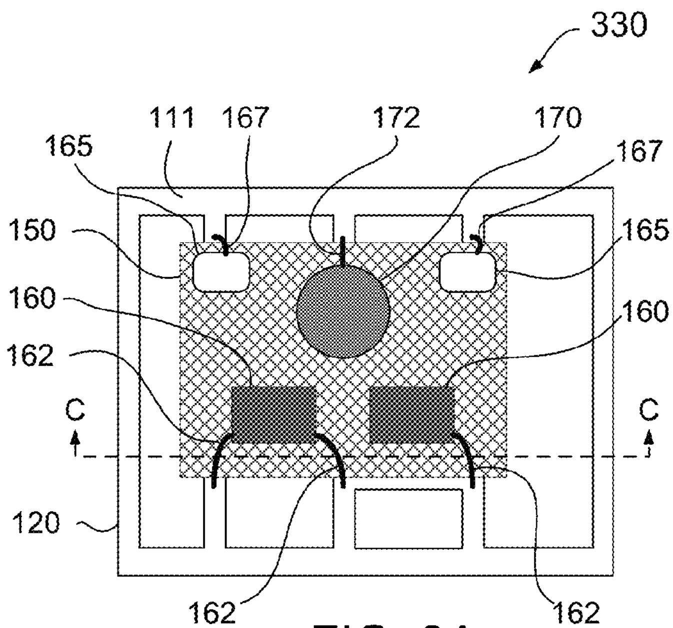
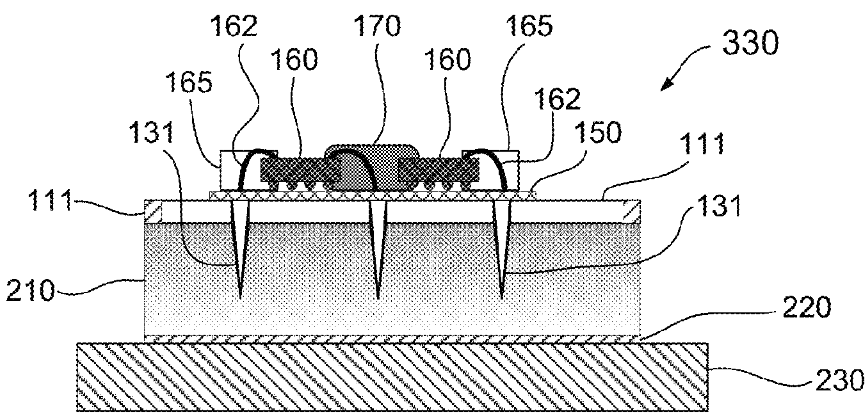
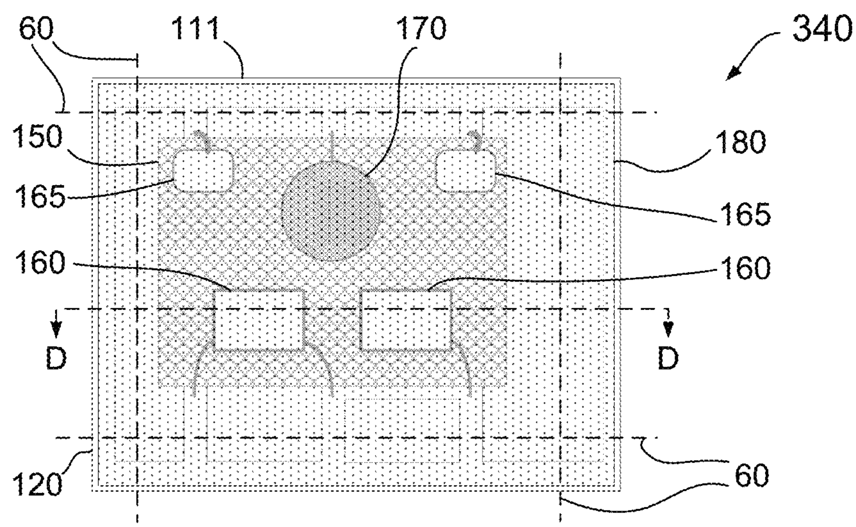


FIG. 9A



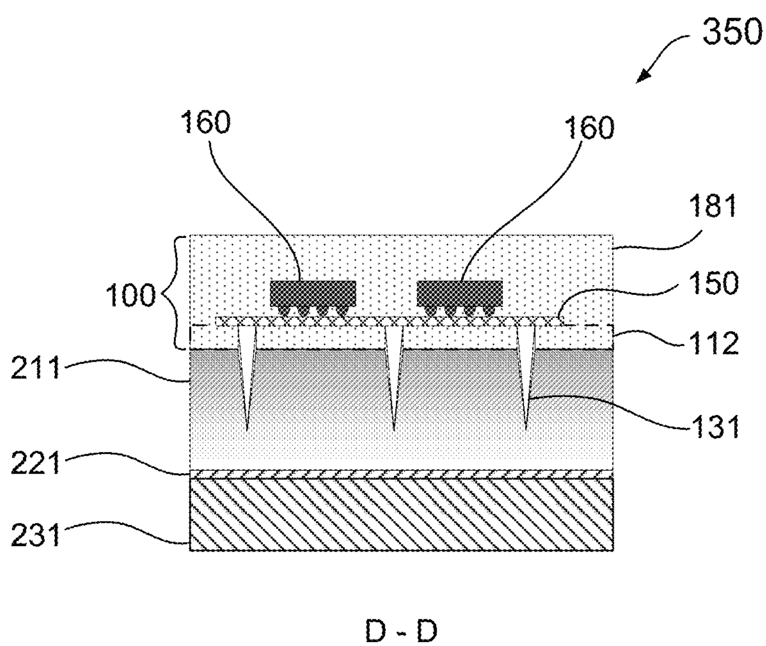
C - C

FIG. 9B



340
60
111
170
150
165
180
165
160
160
D
D
120
60

FIG. 10



350
160
160
181
100
150
112
211
131
221
231
D - D

FIG. 11

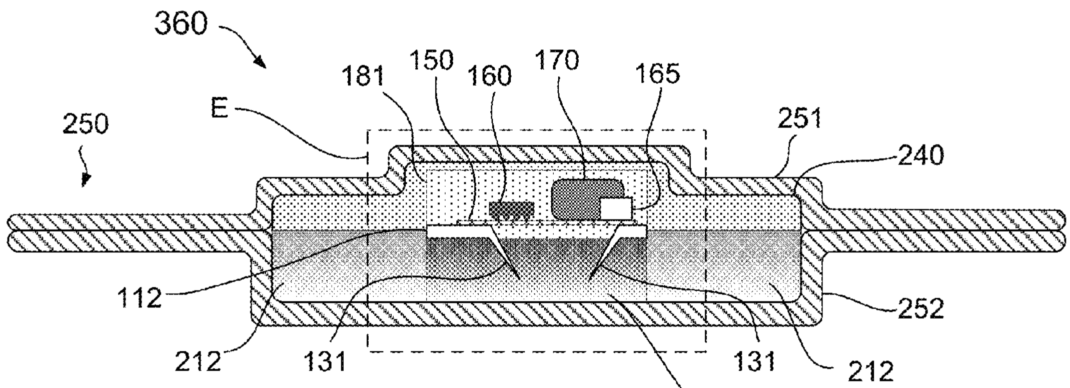


FIG. 12A

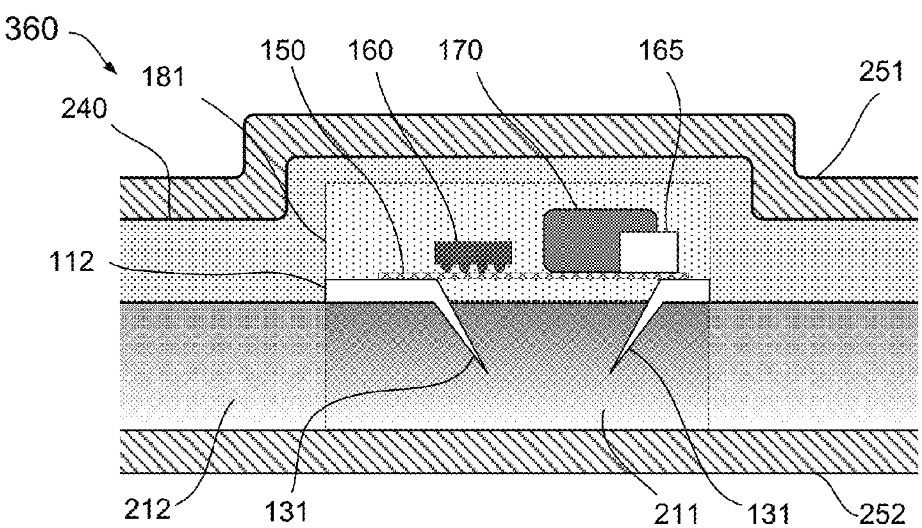


FIG. 12B

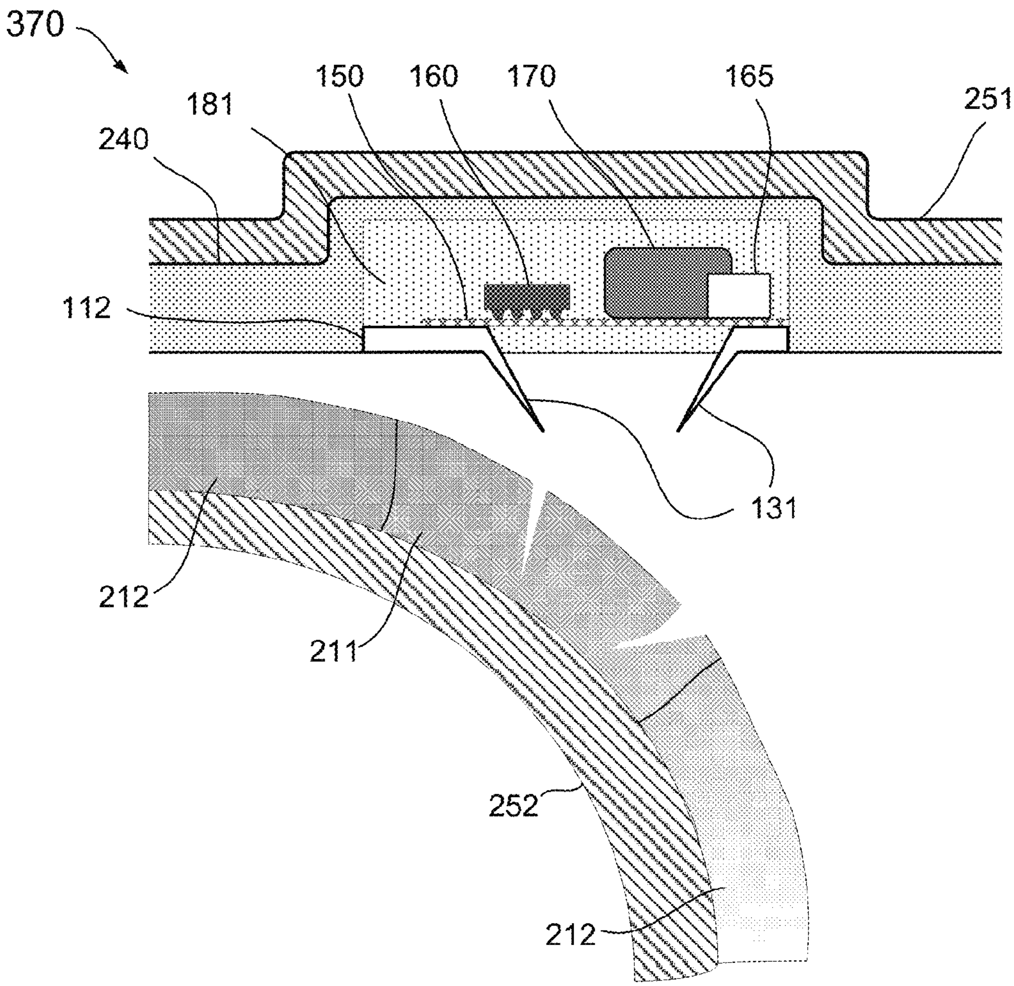


FIG. 13

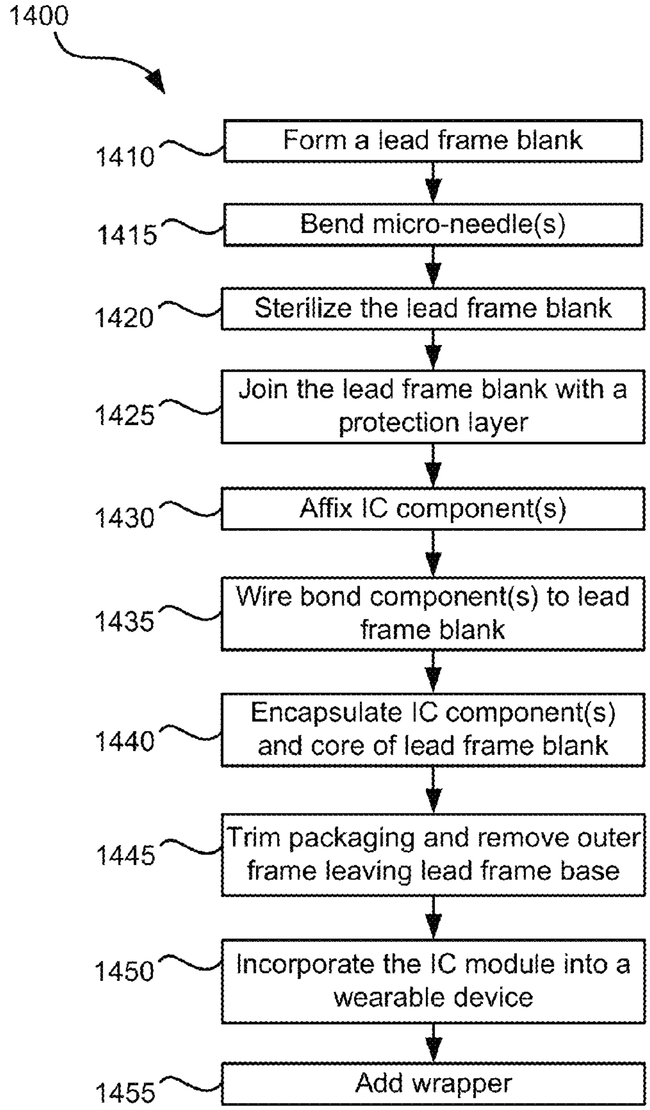

1400
1410
Form a lead frame blank
1415
Bend micro-needle(s)
1420
Sterilize the lead frame blank
1425
Join the lead frame blank with a protection layer
1430
Affix IC component(s)
1435
Wire bond component(s) to lead frame blank
1440
Encapsulate IC component(s) and core of lead frame blank
1445
Trim packaging and remove outer frame leaving lead frame base
1450
Incorporate the IC module into a wearable device
1455
Add wrapper

FIG. 14

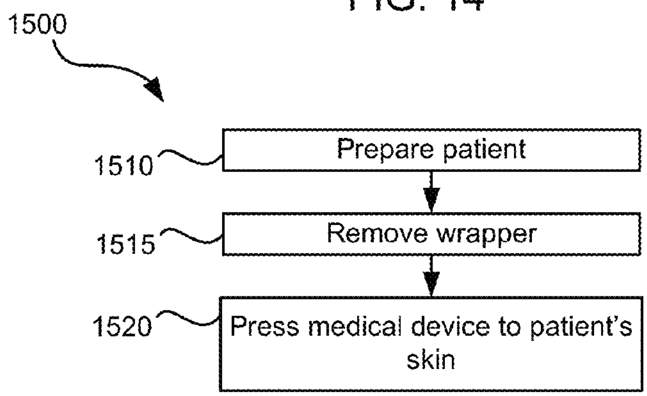

1500
1510
Prepare patient
1515
Remove wrapper
1520
Press medical device to patient's skin

FIG. 15

INTEGRATED CIRCUIT MODULE WITH LEAD FRAME MICRO-NEEDLES

BACKGROUND

Wearable medical devices can sometimes include integrated circuitry for collecting sensor data from the patient wearing the device. The resulting medical device tends to be thicker and bulker than desired for wearing on the patient's body. In addition, costs for such medical device tend to be high due to the varied components and necessary assembly processes. Thus, only patients having the most severe medical conditions warrant the discomfort and costs associated with wearable medical devices.

SUMMARY

In some embodiments, a method of forming an integrated circuit (IC) module with a lead frame micro-needle for a medical device may include forming a lead frame blank including a micro-needle integrally formed therein. The micro-needle may be disposed inward of an outer perimeter of the lead frame blank. The micro-needle may be bent beyond an initial lower side of the lead frame blank. The initial lower side of the lead frame blank may be joined with a protection layer such that the bent micro-needle is embedded in the protection layer. The protection layer may be removably attached to the initial lower side and the bent micro-needle of the lead frame blank. An IC component may be affixed to an upper side of the lead frame blank. In addition, the IC component and at least an upper surface of a core of the lead frame blank may be encapsulated with a molding compound forming a packaging of the IC module. Removal of the protection layer may expose the bent micro-needle projecting away from the packaging.

In some embodiments, the micro-needle may include two opposed micro-needles extending toward one another prior to bending of the two micro-needles beyond the lower side of the lead frame blank. The method may further include sterilizing the lead frame blank before mounting the lead frame blank on the protection layer, such as by applying steam, ethylene oxide, radiation, dry heat, and/or plasma to the lead frame blank. Embodiment methods may further include attaching a substrate to the protection layer, in which a first adhesion strength between the protection layer and the substrate is stronger than a second adhesion strength between the protection layer and the lead frame blank and/or the molding compound, which enables the substrate to be pulled off the packaging with the protection layer remaining attached to the substrate. Embodiment methods may further include pulling the protection layer off the micro-needle and removing an outer frame of the lead frame blank leaving the encapsulated IC component and an inner portion of the lead frame blank.

In some embodiments, the protection layer may be doped with a conductive additive, and the medical device may include a circuit coupled to the conductive additive so that removal of the protection layer activates the IC component.

The medical device may be wearable by a patient, and the IC component may include a sensor coupled to the micro-needle that is configured to sense a parameter when the micro-needle contacts skin of the patient.

Some embodiments include a medical device including an integrated circuit (IC) module coupled to a lead frame including an integrally formed micro-needle. The micro-needle may be formed as a continuous extension of a material forming the lead frame core. The micro-needle may include two opposed micro-needles extending away from the packaging.

The IC module may include a lead frame core including an attachment surface and a micro-needle integrally formed therein. The micro-needle may extend beyond a lower planar surface of the lead frame core. An IC component may be conductively bonded to the attachment surface of the lead frame, and a packaging may encapsulate the IC component and at least an upper portion of the lead frame core so that the micro-needle projects outside of the packaging. The IC component may include a sensor coupled to the micro-needle and configured to sense a parameter when the micro-needle contacts skin of a patient wearing the medical device.

In some embodiments, a protection layer may be removably attached to the lower planar surface of the lead frame core, so that at least a tip of the micro-needle is embedded in the protection layer to keep the micro-needle sterile and protect the needle from deformation during storage and handling. Removal of the protection layer may expose the micro-needle projecting away from the packaging. In some embodiments, the protection layer may be removably attached to the lower planar surface of the lead frame core, and a substrate may be secured to the protection layer with an adhesive with a first adhesion strength that is stronger than a second adhesion strength between the protection layer and the lead frame core. The substrate may be pulled off the packaging with the protection layer remaining attached to the substrate. In addition, the protection layer may be removably attached to the lower planar surface of the lead frame core.

In some embodiments, the protection layer may be doped with a conductive additive, and the medical device may include a circuit coupled to the conductive additive and configured so that removal of the protection layer activates the IC component.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings are presented to aid in the description of embodiments of the disclosure and are provided solely for illustration of the embodiments and not limitation thereof.

FIG. **1** is a side elevation view of an IC module in accordance with various embodiments.

FIG. **2** is a side elevation view of the IC module of FIG. **1** incorporated into a medical device in accordance with various embodiments.

FIG. **3**A illustrates a peel-away substrate on a medical device including an IC module with lead frame micro-needle, in accordance with various embodiments.

FIG. **3**B illustrates a medical device including an IC module with lead frame micro-needle being applied to a patient as a medical sensor patch in accordance with various embodiments.

FIG. **3**C is a relief perspective view of the medical device of FIG. **3**B in accordance with various embodiments.

FIG. **4**A is a top plan view of a lead frame blank in accordance with various embodiments.

FIG. **4**B is a side elevation cross-sectional view at of the lead frame blank of FIG. **4**A, at A-A in accordance with various embodiments.

FIG. **5**A is a cross-sectional side elevation view of the lead frame blank of FIG. **4**B held in a jig in accordance with various embodiments.

FIG. **5**B is a cross-sectional side elevation view of the lead frame blank of FIG. **5**A with the micro-needles bent in accordance with various embodiments.

FIG. **6**A is a top plan view of the bent lead frame blank of FIG. **5**B removed from the jig.

FIG. **6**B is a side elevation view of the bent lead frame blank of FIG. **6**A.

FIG. **6**C is a front elevation cross-sectional view of the bent lead frame blank of FIG. **6**A at B-B.

FIG. **7** is a front elevation cross-sectional view of a first stage lead frame assembly in accordance with various embodiments.

FIG. **8**A is a front elevation cross-sectional view of a second stage lead frame assembly in accordance with various embodiments.

FIG. **8**B is a top view of the second stage lead frame assembly of FIG. **8**A.

FIG. **9**A is a top view of a third stage lead frame assembly in accordance with various embodiments.

FIG. **9**B is a front elevation cross-sectional view of the third stage lead frame assembly of FIG. **9**A at C-C.

FIG. **10** is a top plan view of a fourth stage lead frame assembly in accordance with various embodiments.

FIG. **11** is a rear elevation cross-sectional view of an IC module with lead frame micro-needles in accordance with various embodiments.

FIG. **12**A is a side elevation cross-sectional view of an IC module with lead frame micro-needles in a medical device wrapped in a removable wrapper in accordance with various embodiments.

FIG. **12**B is a relief view of the IC module with lead frame micro-needles of FIG. **12**A, at E.

FIG. **13** is a side elevation cross-sectional view of the medical device of FIG. **12**B with a peel-away substrate being removed in accordance with various embodiments.

FIG. **14** is a process flow diagram illustrating an embodiment method of forming the medical device of FIG. **1**.

FIG. **15** is a process flow diagram illustrating an embodiment method of applying the medical device of FIG. **12**A to a patient.

DETAILED DESCRIPTION

The various embodiments will be described in detail with reference to the accompanying drawings. Wherever possible, the same reference numbers will be used throughout the drawings to refer to the same or like parts. References made to particular examples and implementations are for illustrative purposes, and are not intended to limit the scope of the disclosure or the claims. Alternate embodiments may be devised without departing from the scope of the disclosure. Additionally, well-known elements of the disclosure will not be described in detail or will be omitted so as not to obscure the relevant details of the disclosure.

The words "first," "second," "third," and similar terms are used herein for clarity purposes to distinguish various described elements and are not intended to limit the claims to a particular order or hierarchy of elements.

As used herein, the terms "integrated circuit," abbreviated as "IC," or "IC module," refer to a system of circuit elements, including electrical conductors and components, in which all or some of the circuit elements are inseparably associated and electrically interconnected and may be considered indivisible.

As used herein, the term "lead frame," refers to a metal structure inside an IC module that carries signals from the IC components inside the IC module to the outside. The lead frame may be formed from a conductive metal, such as copper, platinum, or gold, as well as combinations of such materials, such as copper coated with gold. In addition, as part of a manufacturing process, the lead frame may be formed from a lead frame blank that includes an inner core and an outer frame. The IC components may be attached directly to the inner core or an intermediate board, and conductively bonded to the inner core using bond wires. The inner core along with an encapsulating molding compound may form a package holding the IC components inside. The outer frame, which may not be encapsulated by the molding compound, may be removed (e.g., cut-off or separated) from the lead frame blank during a manufacturing process.

Various embodiments configure the lead frame of a unitary encapsulated IC module to include integrally formed micro-needles, thereby enabling the manufacture of low cost wearable medical devices with micro-needles. By forming the lead frame so that it includes micro-needles and configuring the IC module with the lead frame at its base, a portion of the lead frame including the micro-needles may remain exposed to an outside surface of the IC module. In this way, the exposed portion of the lead frame including the micro-needles may be used as conductive contact elements for sensors. In particular, the integrally formed micro-needles may remain exposed and project away from the IC module for penetrating the epidermis to reach subcutaneous tissue or the skin generally. The IC module may include a sensor coupled to the micro-needles for recording, measuring, and/or processing various properties. The IC module may include additional IC components, such as a processor, memory, and a battery.

Various embodiments include a method of forming an IC module with a lead frame micro-needle for a medical device. The method may include forming a lead frame blank including one or more micro-needles and bending those micro-needles beyond an initial lower side of the lead frame blank. Prior to affixing IC components, the lead frame blank may be sterilized using techniques that could be harmful to the IC components. Applying a protection layer to at least the sterilized micro-needles may prevent contamination before contact with the skin of the user. Additional IC components may be affixed to the lead frame blank and a molding compound applied to form a unitary IC module packaging. An outer frame of the lead frame blank not contained within the packaging may be removed.

The IC module with lead frame micro-needles of various embodiments may be incorporated into a wearable medical device, such as a medical sensor patch. In addition, the protection layer of the IC module may be removable. In this way the protection layer may keep the micro-needles (or at least the tips of the micro-needles) clean and/or sterilized, and be removed when ready for use. A substrate, such as paper or tape, secured to the protection layer may be used as a peel-away backing for removing the protection layer when appropriate. In addition, conductive properties included in the protection layer may activate certain IC components of the IC module in response to removal of the protection layer.

FIG. **1** illustrates a side elevation cross-sectional view of an IC module **100** with at least one lead frame micro-needle **131**, in accordance with various embodiments. The IC module **100** may be formed as a unitary module including a circuit board **150**, additional integrated circuits (e.g., semiconductors) **160**, a sensor **165**, a battery **170**, and a lead frame core **112** with micro-needles **131**. In this way, various IC components **150**, **160**, **165**, **170** may be integrated into a single microchip-sized device that includes micro-needles **131** integrally formed with the lead frame core **112**. The lead frame core **112** may provide support and attachment surfaces for the various IC components **150**, **160**, **165**, **170**. The IC components **150**, **160**, **165**, **170** may be encapsulated together, along with at least an upper surface of the lead frame core **112**, by a packaging **181** formed from a molding compound. A lower surface of the lead frame core **112**, including the micro-needles **131**, may not be encapsulated by the packaging **181**. The micro-needles **131**, which are integrally formed with the lead frame core **112**, extend down beyond a lower side of the lead frame core **112** in order to project away from the packaging **181** and be configured to penetrate a patient's skin. Thus the lead frame core **112**, or at least the micro-needles **131**, may be left exposed to contact from outside the packaging **181**, while leaving the other IC components **150**, **160**, **165**, **170** protected by the packaging **181**. So configured, when the base of the IC module **100** is placed in contact with the skin of a patient, the micro-needles **131** may directly contact and partially penetrate the skin. A sensor **165** coupled to at least one micro-needle **131** may be configured to sense or measure a parameter (i.e., a characteristic property) of the patient when the micro-needle comes in contact the skin of the patient.

The relative size and shape of the IC module **100**, including the individual IC components **150**, **160**, **165**, **170**, lead frame core **112** and micro-needles **131**, is intended for illustrative purposes only. The size and shape of any of these elements may be modified as part of the design of the IC module **100** to suit a particular or a general purpose. In particular, the micro-needles **131** will typically be much thinner in width in order to penetrate the skin with little or no pain, and be longer or shorter depending upon the depth of penetration appropriate for the particular patch or sensor. Similarly, the configuration of individual components is for illustrative purposes only, and the size and location of components will depend on the particular design. Thus, fewer or more IC components may be included. In addition, the IC module **100** may be designed to include only one micro-needle **131** or numerous micro-needles **131**, in accordance with various embodiments

FIG. **2** illustrates the IC module **100** of FIG. **1** incorporated into a medical device **200** in accordance with various embodiments. An outer patch structure **240** may be included for aesthetic purposes or to provide additional functional components or properties. For example, while the IC module **100** of FIG. **1** may be used by itself as a medical device, it may be unsightly. Thus, using an outer patch structure **240** may enhance the appearance of the IC module for use as a medical device. Alternatively, a shape of the outer patch structure **240** may be ergonomically formed to fit a particular body part (e.g., shoulder, knee, etc.), simplifying the application and/or removal of the medical device **200** from the patient. As a further example, a larger diameter lower surface **242** of the outer patch structure **240** may include additional adhesive surfaces for sticking to a patient's skin. In addition, the outer patch structure **240** may include one or more optional components **245** appropriate for the particular application or design of the patch. Such optional components **245** may be connected to the lead frame core **112** through optional conductive elements **246**.

The outer patch structure **240** may be formed to any size and need not be a unitary homogeneous structure. The outer patch structure **240** may be provided with a pocket, recess, or chamber **247** for receiving the IC module. The outer patch structure **240** may be permanently secured to the IC module **100** or made to be removably secured to the IC module **100**. For example, the IC module **100** may be a replaceable or disposable component, while the outer patch structure **240** is intended for extended use in combination with replacement IC modules. Alternatively, the outer patch structure **240** may be configured to be disposable and the IC module **100** may be reusable, in which case the IC module **100** may be inserted into the chamber **247** prior to use and removed for reuse before the outer patch structure **240** is discarded.

FIGS. **3A-3C** illustrate an example medical device **200** in various stages of being removed from its protective wrapper for application to a patient. FIG. **3A** illustrates the medical device **200** initially being removed from a protective wrapper **250**. The protective wrapper **250** may include two opposed covers **251**, **252** that sandwich the medical device **200** there between. An individual **10** (e.g., a caregiver or the patient himself) may remove the medical device **200** from the protective wrapper **250** by peeling away the covers **251**, **252** one-at-a-time (as illustrated) or alternatively at the same time. In this way, the protective wrapper **250** may be similar to conventional wrappers used for adhesive bandages with gauze. In the process of peeling away the bottom cover **252**, a protection layer **211** may be pulled away from the medical device **200** thereby exposing the micro-needles **131**.

FIG. **3B** illustrates the example medical device **200** being applied by an individual **10** (e.g., a caregiver) to an upper portion of the back of a patient **11** as a medical sensor patch. As illustrated in this FIGS. **3A** and **3B**, the individual **10** may remove the bottom cover (e.g., **252** in FIG. **3A**) to uncover the micro-needles, and firmly place the medical device **200** on the patient **11**. The individual **10** may then peel away the top cover **25** as shown in FIG. **3B**, leaving only the medical device **200** secured to the patient with the micro-needles **131** penetrating or at least in contact with the skin of the patient **11**.

FIG. **3C** illustrates the portion of the medical device that contacts the patient showing the micro-needles **131**.

The example medical device **200** illustrated in FIG. **3A** has a different shape from example medical device **200** illustrated in FIGS. **3B** and **3C** in order to provide non-limiting examples of how the shapes of such devices may vary.

FIGS. **4A-4B** illustrate an example of lead frame blank **110** that may be used to form an IC module in accordance with various embodiments. FIG. **4A** illustrates a top plan view of the lead frame blank **110**, while FIG. **4B** illustrates a side elevation cross-sectional view of the lead frame blank **110** of FIG. **4A**, at A-A. The lead frame blank **110** may be formed by stamping, pressing, etching, or any other suitable techniques for forming lead frames for electronic circuits. The lead frame blank **110** may be formed from a pliable conductive material, such as but not limited to copper. The lead frame blank **110** may be formed in various shapes and sizes; the rectangular shape shown in FIGS. **4A** and **4B** is for illustrative purposes only.

Referring to the FIG. **4A**, the lead frame blank **110** may include an outer frame **120**, inner leads **125**, inner lands **126**, and one or more integrally formed pre-bent micro-needles **130**. The outer frame **120** may extend around an entire perimeter of the lead frame blank **110**. Although the outer frame **120** is shown as a continuous element, it may have breaks, discontinuities or other variations in form. Inner leads **125** may connect the innermost portions of the lead frame blank **110** to the outer frame **120**. The inner lands **126** may support or connect to IC components or other structures attached thereon, such as an IC board. Inner portions of the inner leads **125** may also act like inner lands **126** for supporting or connecting to IC components or structures as an attachment surface.

The pre-bent micro-needles **130** may be formed inward of an outer perimeter of the lead frame blank **110**, as a continuous extension of a material forming the lead frame blank **110**. In this way, the pre-bent micro-needles **130** may be integrally formed as an unbroken extension (i.e., without interruption) of one or more other lead frame elements (e.g., outer frame **120**, inner leads **125**, or inner lands **126**). In addition, the pre-bent micro-needles **130** may be sharpened to a point or formed thin and pointy enough to penetrate skin. For example, if very sharp micro-needles are desired, the pre-bent micro-needles **130** may be etched to form tiny needle like structures (i.e., cylindrical forms ending in a point) or triangular projections. The tips of the pre-bent micro-needles **130** (or at least one tip) may be coated with biologically compatible conductive layer, such as platinum. The embodiment illustrated in FIG. **4**A includes six pre-bent micro-needles **130**, which are grouped into three pairs. The pairs of pre-bent micro-needles **130** include two opposed pre-bent micro-needles **130** extending toward one another. The endpoints of the paired pre-bent micro-needles **130** are spaced apart by a distance X, which forms a gap **135**, which may be sized to meet various functional and/or structural requirements. Alternatively, the gap **135** may be eliminated, so that the endpoints touch or even join in the center. At a later stage in the process flow of forming the IC module illustrated FIGS. **5**A and **5**B, the pre-bent micro-needles **130** are bent to an orientation appropriate for penetrating skin, such as using a press tool (the outline of which is indicated at **50** in FIG. **4**A).

Referring to FIG. **4**B, the pre-bent micro-needles **130** may include micro-needle inner portions **130***a* closest to the gap **135** and micro-needle outer portions **130***b* closest to the outer frame **120**. In this embodiment, the pre-bent micro-needles **130** are tapered, with a thicker part at the micro-needle outer portion **130***b* tapering to a point at the end of the micro-needle inner portion **130***a*. The taper is also illustrated as extending from an initial upper side **139** to an initial lower side **137** of the pre-bent micro-needles **130**. Alternatively, the taper may meet in the middle between the lower and upper sides **137**, **139**, or taper in the opposite direction (i.e., being thickest at the lower side **137** and tapering toward a point at the upper side **139**).

FIGS. **5**A and **5**B illustrate two steps of an embodiment method of bending the pre-bent micro-needles **130**. FIG. **5**A illustrates a cross-sectional side elevation view of the lead frame blank **110** held in a jig **57** for bending micro-needles. Above the lead frame blank **110** is a pressing tool **52** (the outline of which is denoted as **50** in FIG. **4**A). The micro-needles **130** may be bent by moving the pressing tool **52** through the gap **135** as indicated by the arrows in FIG. **5**A to the final position illustrated in FIG. **5**B. As the pressing tool **52** continues moving downwards through the gap **135**, its angled edges engage the upper surfaces of the micro-needle inner portions **130***a* bending them down. The pressing tool **52** may be designed to bend the micro-needle inner portions **130***a* beyond a lower planar surface (e.g., lower side **137** of FIG. **4**B) of the lead frame blank **110**, less than 90° to form bent micro-needles **131** (which is referred to herein as a bent lead frame blank **111**). An angle of the bent micro-needles **131** may be greater or less than that shown. For example, the bent micro-needles **131** may be bent less than that shown (i.e., still pointing toward one another), may be bent more so they are approximately perpendicular to the planer portions of the bent lead frame blank **111** (i.e., pointing parallel to one another), or bent past a perpendicular orientation (i.e., pointing outwardly from one another).

FIGS. **6**A-**6**C illustrate various views of the bent lead frame blank **111** of FIG. **5**B. In particular, FIG. **6**A illustrates a top plan view and FIG. **6**B illustrates a side elevation view of the bent lead frame blank **111**. FIG. **6**C illustrates a front elevation cross-sectional view of the bent lead frame blank of FIG. **6**A, at B-B. Although the outer frame **120** is generally unchanged, the tips of the pairs of bent micro-needles **131** are further separated apart by distance Y, presenting a wider gap **136** between them.

Once the bent lead frame blank **111** is formed, it may be subjected to one or more cleaning and/or sterilization operations, particularly for sterilizing the micro-needles **131** that may contact and penetrate a patient's skin. Medical devices intended to penetrate the skin during use should be well cleaned and sterilized to avoid exposing a patient to harmful chemicals or metals and to prevent infection. Numerous sterilization techniques may be used, including steam, ethylene oxide, radiation, dry heat, or plasma that are known to be effective in sterilizing needles and similar medical devices. An advantage of sterilizing the bent lead frame blank **111** at this point is that no electronic components have yet been attached. Attaching electronic components before sterilization may limit the types of sterilization techniques that can be used to those that will not damage integrated circuits, as well as add expense to the sterilization process because of the extra care involved in handling the attached electronic components. Optionally, the bent micro-needles **131** or other portions of the lower side (e.g., **137** in FIG. **4**B) intended to contact a patient's skin may be additionally treated at this stage. For example, additional sterilization, a coating for biocompatibility/drug delivery, or other finishes may be applied to the bent micro-needles **131** or other portions of the lower side. For example, antimicrobial or antibiotic coatings may be applied for subcutaneous application.

FIG. **7** illustrates the bent lead frame blank **111** of FIG. **6**C joined with other layers to form a first stage lead frame assembly **310** in accordance with various embodiments. The first stage lead frame assembly **310** may be assembled by a process of joining the various layers. A process of joining the various layers may bring the bent lead frame blank **111** into contact with a stationary protection layer **210**, the stationary protection layer **210** into contact with the bent lead frame blank **111**, or the two elements **111**, **210** may both be moved toward one another. In this embodiment, the process of joining the various layers embeds the bent lead frame blank **111**, and particularly the bent micro-needles **131**, into the protection layer **210**. The protection layer **210** may maintain the sterilized condition of the bent micro-needles **131**. In addition, the protection layer **210** may eventually help prevent a patient or caregiver from unintentionally sticking themselves or others with the bent micro-needles **131**. The protection layer **210** may also protect the micro-needles **131** from being bent during later manufacturing steps or handling and packaging.

The protection layer **210** may be supported by a carrier **230**. The carrier **230** may be a rigid support surface, such as glass or ceramic, or a removable substrate, such as paper, fabric, or tape, supported by another subsurface (not shown). A joining layer **220** may join the carrier **230** to the protection layer **210**. The joining layer **220** may be an adhesive layer used to hold the protection layer **210** to the carrier **230** when the carrier **230** is subsequently removed. Alternatively, the joining layer **220** may be a release layer for encouraging the carrier **230** to easily separate from the protection layer **210**.

The protection layer **210** may be formed of an acrylic rubber or silicone, with additives for balancing the adhesion strength. In this way the protection layer **210** may have a low adhesion property, enabling it to gently stick to the bent lead frame blank **111**, while being able to be removed later (i.e., demounting). In addition, the protection layer **210** may be initially applied in a softened state, so that the bent micro-needles **131** may be embedded therein, and later hardened through chemical or thermal treatments. The protection layer **210** need not be rigid but may have a high enough compression strength to support the bent lead frame blank on its own. The protection layer **210** may be formed of a thermoplastic, such as a non-photodefinable polyimide adhesive (e.g., HD-**3007** series materials from Hitachi DuPOnt (HD) MicroSystems™, Cupertino, Calif.), or a UV curable polymer, such as a structural adhesive (e.g., 3M™ Scotch-Weld™ Structural Plastic Adhesive DP8010, 3M, St. Paul, Minn.).

FIGS. **8**A and **8***b* illustrate different views of a second stage lead frame assembly **320** in accordance with various embodiments. In particular, FIG. **8**A illustrates a front elevation cross-sectional view similar to the first stage lead frame assembly of FIG. **7**, but with additional elements attached thereto. FIG. **8**B illustrates a top view of the bent lead frame assembly of FIG. **8**A. The order of particular components/elements added may vary depending on the design and desired configuration of the eventual IC module.

A circuit (e.g., IC) board **150** may be one of the initial elements affixed to form the second stage lead frame assembly **320**. The circuit board **150** may be a sturdy flame-resistant material, such as a glass-reinforced epoxy laminate sheet (e.g., an FR-4 grade printed circuit board). The circuit board **150** may be secured with an adhesive to lands of the bent lead frame blank **111** (e.g., **125**, **126** in FIG. **4**A). Other elements, such as one or more integrated circuits **160**, one or more sensors **165**, and a battery **170** may also be added. The integrated circuits **160** are semiconductors designed and formed to provide a given circuit function. Each integrated circuit **160** may include a set of electronic circuits on one small plate ("chip") of semiconductor material, normally silicon, which may be made much smaller than a discrete circuit made from independent components. The integrated circuits **160** may be affixed to the circuit board **150** using thermal conductive adhesives. Fewer or additional integrated circuits **160** may be affixed to form the second stage lead frame assembly **320**. In addition, passives and other elements may be added. For example, more than one sensor **165** may be included. The sensors **165** may be redundant or measure different properties. In addition, the battery **170** may supply power to the various IC components. The battery **170** may be a button-cell battery suited to the various IC components that might use it.

Optionally, the IC components may include a special purpose processor for handling data collected by sensors. Additionally, components such as a transceiver, or at least a transmitter, may be included in order to transmit information collected and/or receive commands related to the medical device. In addition, other elements such as a communication or power supply port may be included.

FIGS. **9**A and **9**B illustrate different views of a third stage lead frame assembly **330**, in accordance with various embodiments. In particular, FIG. **9**A illustrates a top view similar to the second stage lead frame assembly **320** of FIGS. **8**A and **8**B, but with the various IC components wire-bonding to the bent lead frame blank **111**. FIG. **9**B illustrates a front elevation cross-sectional view of the third stage lead frame assembly **330** of FIG. **9**A, at C-C. The wire-bonding may connect the individual IC components **160**, **165**, **170** to the bent lead frame blank **111**, providing an electrical connection. For example, first conductive wires **162** may connect the integrated circuits **160** to a first portion of the bent lead frame blank **111**, second conductive wires **172** may connect the battery **170** to a second portion of the bent lead frame blank **111**, and third conductive wires **167** may connect the sensors **165** to a third portion of the bent lead frame blank **111**. The conductive wires **162**, **167**, **172** may be gold or other material used for providing reliable electrical conductivity between the bent lead frame blank **111** and the respective components **160**, **165**, **170**. The first, second, and third portions of the bent lead frame blank **111** to which the conductive wires **162**, **167**, **172** are attached may be portions of the leads or lands (e.g., **125**, **126** in FIG. **4**A) of the bent lead frame blank **111**.

FIG. **10** illustrates a top plan view of a fourth stage lead frame assembly **340**, in accordance with various embodiments. FIG. **10** is similar to the view of the third stage lead frame assembly **330** of FIG. **9**A, but with a molding compound **180** added. The molding compound **180** encapsulates the IC components **150**, **160**, **165**, **170** and may encapsulate portions of the bent lead frame blank **111**. The molding compound **180** may be applied by various methods, such as injection molding, transfer molding, and other techniques. Once hardened, the molding compound **180** may support and encase the IC components **150**, **160**, **165**, **170**, preventing physical damage and corrosion. The hardened molding compound **180** forms a packaging of the IC module. The molding compound **180** may be in epoxy plastic suited to provide adequate protection of the IC components **150**, **160**, **165**, **170** and support for the bent micro-needles **131** projecting outside and away from the packaging. Optionally, openings or windows (not shown) may be formed in the packaging for elements such as light emitters, sensors and/or switches.

Once the molding compound **180** is hardened or at least semi-hardened, the third stage lead frame assembly **330** may be trimmed. The cut lines **60** indicate where the third stage lead frame assembly **330** may be trimmed. Such trimming may not only reduce the size of the third stage lead frame assembly **330** but also remove the outer frame **120** of the bent lead frame blank **111**. Removal of the outer frame **120** leaves the encapsulated IC components **150**, **160**, **165**, **170** and inner lead frame portions. The hardened and trimmed molding compound **180** may be the intended packaging for the final IC module (e.g., **100** in FIG. **1**).

FIG. **11** illustrates a rear elevation cross-sectional view of a fifth stage lead frame assembly **350**, in accordance with various embodiments. FIG. **11** is a cross-sectional view of an IC module **100** with lead frame micro-needles at cross section D-D in FIG. **10** after the trimming at cut lines **60**, in accordance with various embodiments. The trimmed assembly now includes the IC module **108**, trimmed protection layer **211**, the trimmed joining layer **221**, and the trimmed carrier layer **231**. The trimmed joining layer **221** and the trimmed carrier layer **231** are optional and may not be used in designs using a more hard trimmed joining layer **221**. At this stage, the lead frame assembly **350** may be tested using conventional IC testing techniques. Optionally, the trimmed joining layer **211** may be removed for testing the micro-needles **131**. After such testing, a replacement protection layer may be added over the micro-needles **131**. The trimmed joining layer **211** may serve to protect the tips of the micro-needles **131** embedded therein from bending, poking people, and being contaminated. In some embodiments, the tips of the micro-needles **131** may need to remain clean and hygienic enough for medical purposes.

FIGS. **12**A and **12**B illustrate an IC module with lead frame micro-needles implemented in a medical device wrapped in a removable substrate, in accordance with various embodiments. In particular, FIG. **12**A illustrates a cross-sectional view of the IC module **100** of FIG. **1**, in a outer patch structure **240** wrapped in a removable wrapper **250**. FIG. **12**B is a detail view of the IC module with lead frame micro-needles of FIG. **12**A, at E. Application of the wrapper **250** may form a final stage assembly **360**. The wrapper **250** may be formed from two opposed covers **251**, **252** enveloping the outer patch structure **240** and protection layers **211**, **212** within. In the embodiment of FIGS. **12**A and **12**B, the trimmed protection layer **211** and trimmed carrier layer **231** (FIG. **11**) are either not included or have been removed prior to wrapping. In addition, a peripheral protection layer **212** may be added for support. Optionally, the peripheral protection layer **212** need not be included or may have a tapered profile to reduce the size of the final stage assembly **360**. The wrapper **250** may be added using traditional patch technology web conversion techniques.

FIG. **13** illustrates a final stage assembly of FIG. **12**B with the bottom wrapper cover **252** being pulled away, pulling with it the protection layers **211**, **212** during the opening stage **370** of the wrapper in accordance with various embodiments. The bottom wrapper cover **252** may be peeled off just before applying the medical device **200** to a patient. The opening stage **370** may include peeling away at least one of the two opposed wrapper covers **251**, **252**. The adhesive between the bottom wrapper cover **252** and the protection layers **211**, **212** may have a first adhesion strength that is stronger than a second adhesion strength between the protection layers **211**, **212** and the lower components of the outer patch structure **240**. Those lower components may include the underside of the outer patch structure **240**, portions of the trimmed lead frame core **112**, portions of the trimmed packaging **181**, and the micro-needles **131**.

The trimmed protection layer **211**, which protects the micro-needles **131**, may be doped with a conductive additive (i.e., a conductive doping), such as silver (Ag). The conductive doping may make the trimmed protection layer **211** conductive. The IC module may be designed to detect when the protection layer is removed, which may be used to trigger the activation of other elements of the IC module. For example, the doped adhesive may maintain a closed-circuit of the IC components, which upon opening by removal of the protection layer will activate other IC components or functions. When the doped protection layer has been removed, the micro-needles **131** are exposed and the device is ready to be applied to a patient's skin.

FIG. **14** illustrates an embodiment method **1400** of forming the medical device of FIG. **1**, in accordance with various embodiments. In block **1410**, a lead frame blank may be formed using any known method for forming lead frames.

In block **1415**, the lead frame blank may be bent to form the micro-needles, such as described with reference to FIGS. **5**A-**5**B.

In block **1420**, the lead frame blank may be cleaned and sterilized. Sterilization process may include cleaning and applying more than one stage of sterilization treatments to the bent lead frame blank. As described above, sterilization techniques such as the application of steam, ethylene oxide, radiation, dry heat or plasma may be used.

In block **1425**, the lead frame blank may be joined with a protection layer. For example, an initial lower side of the lead frame blank may be joined with the protection layer such that the bent micro-needles are embedded in the protection layer. This protection layer may be removably attached to that initial lower side of the lead frame blank and the micro-needles. For example, the process described with reference to FIG. **7** may be used for adding the protection layer to the lead frame blank.

In block **1430**, one or more IC components may be affixed to an upper side of the lead frame blank. Affixing the IC components may include securing the IC components to the lead frame blank, and coupling components to one another. For example, the process described with reference to FIGS. **8**A-**8**B may be used to affix the IC components to the lead frame blank.

In block **1435**, the IC components may be wire bonded to the lead frame blank. For example, the process described with described to FIGS. **9**A-**9**B may be used to wire bond the IC components to the lead frame blank.

In block **1440**, the IC components and at least an upper surface of a core of the lead frame blank may be encapsulated with a molding compound. This encapsulation may form a packaging of the IC module. For example, the process described with reference to FIG. **10** may be used to encapsulate the one or more IC components and a portion of the lead frame blank.

In block **1445**, the packaging of the IC module may be trimmed, which may remove an outer frame of the lead frame blank. Removing the outer frame of the lead frame blank may leave the encapsulated IC component(s) and inner portions of the lead frame blank to form the IC module. For example, the process described with reference to FIGS. **10-11** may be used to trim the assembly and the packaging of the IC module.

In block **1450**, the IC module may be incorporated into a wearable device, such as in medical sensor patch. For example, the IC module may be inserted into a medical patch structure, such as that described with reference to FIG. **2**.

In block **1455**, the medical device may be enveloped in a removable wrapper. For example, the wrapper described with reference to FIG. **12**A may be applied to the medical device. The wrapper may be the final outer packaging used to deliver the medical device to medical providers and/or patients.

FIG. **15** illustrates an embodiment method **1500** of applying the medical device of FIG. **12**A to a patient, in accordance with various embodiments. In block **1510**, the patient may be prepared for receiving medical device. Preparation may include pulling away a removing clothes, cleaning the skin, and generally clearing the area where the medical device will be applied. In block **1515**, the wrapper enveloping the medical device may be removed. For example, the process described with reference to FIGS. **3**A-**3**C and **13** may be applied to remove the wrapper. As described above with reference to FIG. **13**, the wrapper may be removable so that it also removes the protective layer covering the micro-needles **131**. In block **1520**, the medical device may be pressed against the patient's skin. An adhesive on the underside of the medical device may hold the medical device in place. In addition, pressing the medical device against the patient's skin may cause the micro-needles **131** to penetrate the patient's skin. In this way, sensors of the medical device coupled to the micro-needles may take appropriate measurements.

Any reference to claim elements in the singular, for example, using the articles "a," "an" or "the" is not to be construed as limiting the element to the singular.

One skilled in the relevant art will recognize that many possible modifications and combinations of the aspects of the disclosed embodiments may be used, while still employing the same basic underlying mechanisms and methodologies. The foregoing description, for purposes of explanation, has been written with references to specific embodiments. However, the illustrative discussions above are not intended to be exhaustive or to limit the disclosure to the precise forms disclosed. Many modifications and variations are possible in view of the above teachings. The embodiments were chosen and described to explain the principles of the disclosure and their practical applications, and to enable others skilled in the art to best utilize the disclosure and various embodiments with various modifications as suited to the particular use contemplated. Thus, the present disclosure is not intended to be limited to the embodiments and individual aspects of the disclosed technologies shown and described herein, but is to be accorded the widest scope consistent with the following claims and the principles and novel features disclosed herein.

What is claimed is:

1. An integrated circuit (IC) module with lead frame micro-needle for a medical device, comprising:

a lead frame core including an attachment surface and a micro-needle integrally formed therein, the micro-needle extending beyond a lower planar surface of the lead frame core;

an IC component conductively bonded to the attachment surface; and

a packaging encapsulating the IC component and at least an upper portion of the lead frame core, wherein the micro-needle projects outside of the packaging.

2. The IC module of claim 1, further comprising:

a protection layer removably attached to the lower planar surface of the lead frame core, wherein at least a tip of the micro-needle is embedded in the protection layer.

3. The IC module of claim 2, wherein removal of the protection layer exposes the micro-needle projecting away from the packaging.

4. The IC module of claim 2, wherein at least the tip of the micro-needle is kept sterile by the protection layer.

5. The IC module of claim 1, wherein the micro-needle is formed as a continuous extension of a material forming the lead frame core.

6. The IC module of claim 1, wherein the micro-needle comprises two opposed micro-needles extending away from the packaging.

7. The IC module of claim 1, further comprising:

a protection layer removably attached to the lower planar surface of the lead frame core; and

a substrate secured to the protection layer, wherein a first adhesion strength between the protection layer and the substrate is stronger than a second adhesion strength between the protection layer and the lead frame core.

8. The IC module of claim 7, wherein the substrate is configured so that when the substrate is pulled off the packaging, the protection layer remains attached to the substrate.

9. The IC module of claim 1, further comprising:

a protection layer removably attached to the lower planar surface of the lead frame core, wherein the protection layer is doped with a conductive additive; and

a circuit coupled to the conductive additive and configured to activate the IC component when the protection layer with the conductive additive is removed from the lower planar surface of the lead frame core.

10. The IC module of claim 1, further comprising a sensor coupled to the micro-needle and configured to sense a parameter when the micro-needle contacts skin of a patient.

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